

**We Claim:**

- 1           1.       A process for preparing an oral dosage form containing modafinil, the  
2 process comprising:  
3                   forming a dosage form comprising  
4                         about 7% - 25% by weight of modafinil particles have diameters  
5                         greater than 220  $\mu\text{m}$ ; and  
6                         about 75% - 93% by weight of modafinil particles have diameters  
7                         less than 220  $\mu\text{m}$ .
- 1           2.       The process according to claim 1 wherein about 7% by weight of the  
2 modafinil particles have diameters greater than 220  $\mu\text{m}$  and about 93% by weight of the  
3 modafinil particles have diameters less than 220  $\mu\text{m}$ .
- 1           3.       The process according to claim 1 wherein about 10% by weight of the  
2 modafinil particles have diameters greater than 220  $\mu\text{m}$  and about 90% by weight of the  
3 modafinil particles have diameters less than 220  $\mu\text{m}$ .
- 1           4.       The process according to claim 1 wherein about 15% by weight of the  
2 modafinil particles have diameters greater than 220  $\mu\text{m}$  and about 85% by weight of the  
3 modafinil particles have diameters less than 220  $\mu\text{m}$ .
- 1           5.       The process according to claim 1 wherein the specific surface area of the  
2 modafinil particles is at least 0.2  $\text{m}^2/\text{gm}$ .
- 1           6.       The process according to claim 1 wherein the dosage form releases at least  
2 75% of the modafinil in about 45 minutes.
- 1           7.       The process according to claim 1 wherein the dosage form comprises a  
2 tablet or a capsule.
- 1           8.       The process according to claim 1 further comprising one or more  
2 pharmaceutically acceptable excipients.
- 1           9.       The process according to claim 8 wherein the pharmaceutically acceptable  
2 excipients comprise one or more of binders, diluents, disintegrants, surfactants, lubricants,  
3 glidants, and coloring agents.
- 1           10.      The process according to claim 1 wherein forming the dosage form  
2 comprises

3           blending the modafinil particles with one or more pharmaceutically inert excipients  
4   to form a blend,

5           granulating the blend to form granules,

6           blending the granules with one or more pharmaceutically inert excipients, and

7           compressing or filling into a solid dosage form.

1           11.    The process according to claim 10 wherein granulating comprises wet  
2   granulation.

1           12.    The process according to claim 10 wherein granulating comprises dry  
2   granulation.

1           13.    The process according to claim 10 wherein the dosage form comprises a  
2   tablet and the process further comprises coating the tablet.

1           14.    The process according to claim 1, wherein forming the dosage form  
2   comprises blending the modafinil particles with one or more pharmaceutically inert  
3   excipients to form a blend and compressing the blend or filling the blend into a solid  
4   dosage form.

1           15.    The process according to claim 1 wherein forming a dosage form further  
2   comprises mixing the modafinil particles in geometric progression with one or more  
3   pharmaceutically acceptable excipients to form a blend.

1           16.    The process according to claim 15 further comprising:

2           granulating the blend to form granules;

3           optionally drying the granules;

4           sizing the granules;

5           mixing the sized granules with one or more pharmaceutically acceptable  
6   excipients; and

7           compressing into a tablet.

1           17.    An oral dosage form of modafinil comprising:

2           about 7% to 25% by weight of modafinil particles have diameters greater than 220  
3   μm; and

4           about 93% to 75% by weight of modafinil particles have diameters less than 220  
5   μm.

1           18.    The oral dosage form according to claim 17 wherein about 7% by weight of  
2   the modafinil particles have diameters greater than 220 μm and about 93% by weight of  
3   the modafinil particles have diameters less than 220 μm.

1           19.    The oral dosage form according to claim 17 wherein about 10% by weight  
2   of the modafinil particles have diameters greater than 220 μm and about 90% by weight of  
3   the modafinil particles have diameters less than 220 μm.

1           20.    The oral dosage form according to claim 17 wherein about 15% by weight  
2   of the modafinil particles have diameters greater than 220 μm and about 85% by weight of  
3   the modafinil particles have diameters less than 220 μm.

1           21.    The oral dosage form according to claim 17 wherein the specific surface  
2   area of the modafinil particles is at least 0.2 m<sup>2</sup>/gm.

1           22.    The oral dosage form according to claim 17 wherein the dosage form  
2   releases at least 75% of the modafinil in about 45 minutes.

1           23.    The oral dosage form according to claim 17 wherein the dosage form  
2   comprises a tablet or capsule.

1           24.    The oral dosage form according to claim 17 further comprising one or more  
2   pharmaceutically acceptable excipients.

1           25.    The oral dosage form according to claim 24 wherein the pharmaceutically  
2   acceptable excipients comprises one or more of binders, diluents, disintegrants,  
3   surfactants, lubricants, glidants, and coloring agents.

1           26.    A method of treating a condition using modafinil, the method of treating  
2   comprising:

3           providing an oral dosage form of modafinil comprising

4                    about 7% to 25% by weight of modafinil particles have diameters greater  
5           than 220 μm; and

6                    about 93% to 75% by weight of modafinil particles have diameters less  
7           than 220 μm.

- 1           27.     The method according to claim 25 wherein about 7% by weight of the  
2     modafinil particles have diameters greater than 220  $\mu\text{m}$  and about 93% by weight of the  
3     modafinil particles have diameters less than 220  $\mu\text{m}$ .
- 1           28.     The method according to claim 25 wherein about 10% by weight of the  
2     modafinil particles have diameters greater than 220  $\mu\text{m}$  and about 90% by weight of the  
3     modafinil particles have diameters less than 220  $\mu\text{m}$ .
- 1           29.     The method according to claim 25 wherein about 15% by weight of the  
2     modafinil particles have diameters greater than 220  $\mu\text{m}$  and about 85% by weight of the  
3     modafinil particles have diameters less than 220  $\mu\text{m}$ .
- 1           30.     The method according to claim 25 wherein the specific surface area of the  
2     total modafinil particles is at least 0.2  $\text{m}^2/\text{gm}$ .
- 1           31.     The method according to claim 25 wherein the dosage form releases at least  
2     75% of the modafinil in about 45 minutes.
- 1           32.     The method according to claim 25 wherein the dosage form comprises a  
2     tablet or capsule.
- 1           33.     The method according to claim 25 further comprising one or more  
2     pharmaceutically acceptable excipients.
- 1           34.     The method according to claim 33 wherein the pharmaceutically acceptable  
2     excipients comprise one or more of binders, diluents, disintegrants, surfactants, lubricants,  
3     glidants, and coloring agents.
- 1           35.     The method according to claim 25 wherein the condition comprises one or  
2     more of narcolepsy and idiopathic hypersomnia.
- 1           36.     An oral dosage form of modafinil comprising an intragranular portion and  
2     an extragranular portion:  
3                 the intragranular portion comprising about 7% to 25% by weight of modafinil  
4     particles having diameters greater than 220  $\mu\text{m}$ , about 93% to 75% by weight of modafinil  
5     particles having diameters less than 220  $\mu\text{m}$ , and one or more pharmaceutically acceptable  
6     excipients; and  
7                 the extragranular portion comprising one or more pharmaceutically acceptable  
8     excipients.

1           37.     The oral dosage form according to claim 36 wherein the oral dosage form  
2 releases one or more of between 48% and 81% of the modafinil within 15 minutes,  
3 between 68% and 87% of the modafinil within 30 minutes, between 76% and 95% of the  
4 modafinil within 45 minutes, between 84% and 97% of the modafinil within 60 minutes,  
5 and between 89% and 98% of the modafinil within 90 minutes.

1           38.     The oral dosage form according to claim 37 wherein the modafinil is  
2 released in a USP Apparatus II, in 900 ml of water, and stirred at 50 rpm.

1           39.     The oral dosage form according to claim 36 wherein the oral dosage form is  
2 provided with labeling for one or more of wakefulness promotion, to improve wakefulness  
3 in patients with excessive daytime sleepiness associated with narcolepsy, and idiopathic  
4 hypersomnia.